DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

5157

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

February 6, 2001

WARNING LETTER
CHI-18-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michael Hummermeier, Owner
Hummermeier Farm
9559 West Babbs Grove Road
Pearl City, IL 61062

Dear Mr. Hummermeier:

An investigation of your beef operation conducted 10/5-6/00, found that a downer cow from your establishment was offered for sale for slaughter as human food in violation of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about 1/3/00, you sold a cow for slaughter as human food to [redacted]. USDA analysis of tissue samples collected from that animal identified the presence of [redacted] parts per million (ppm) Gentamicin and [redacted] ppm penicillin in the kidney tissue. There is no established tolerance for Gentamicin in cattle (Title 21, Code of Federal Regulations, Part 556.300). The established regulatory action level for penicillin in cattle is 0.5 ppm (Title 21, Code of Federal Regulations, Part 556.510). The presence of these drugs in the edible tissue from this animal causes the food to be adulterated under the Act.

You also lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues from edible tissue. You need to implement a system in which to record and maintain permanent drug treatment records that will adequately identify drug treated animals.

The above is not intended as an all-inclusive list of violations. As a producer of animals offered for human consumption, you are responsible for assuring that your overall operation and the food products you produce for distribution are in compliance with the law.

You should take prompt action to correct the violation, and you should establish procedures whereby such violation does not recur. Failure to promptly correct the violation may result in regulatory action without further notice, such as seizure and/or injunction. This letter constitutes notification under the law.

Please advise this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Richard Harrison, Director, Compliance Branch.

Sincerely,

\s\
Raymond V. Mlecko
District Director

cc: Manzoor Chaudry, DVM
Branch Chief, Residue Staff
Food Safety and Inspection Service
US Dept. of Agriculture
Technical Service Center
106 S. 15th St., Ste 904
Omaha, NE 68102

cc: Richard Hull, DVM
Chief Veterinarian
Bureau of Animal Health
Division of Animal Industries
Illinois Department of Agriculture
P.O. Box 19281
Springfield, IL 62794-9281

cc: Mark Ringler
Bureau Manager
Bureau of Agricultural Products Inspection
Division of Agricultural Industry Regulations (DAIR)
Illinois Department of Agriculture
P.O. Box 19281
Springfield, IL 62794-9281